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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,685

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EXAMINER

HELM, CARALYNNE E

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,685	Applicant(s) FUKUHIRA ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-12 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of group II without traverse in the reply filed on May 22, 2008 is acknowledged. Upon further consideration, the additional species election that was originally required is hereby withdrawn. The restriction is still deemed proper and thereby made FINAL.

Claim 1-3 and 13-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Objections

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Presently instant claim 10 recites a single compound as opposed to a genus of compounds. Instant claim 11 attempts to further define the compound of 10, but instead redefines the phospholipid present in the composition, changing it from L- α -phosphatidyl ethanolamine to L- α -phosphatidyl ethanolamine dioleoyl.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl ethanolamine dioleoyl, phosphatidyl serine, and phosphatidyl glycerol which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim 9 is directed to encompass derivatives, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

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'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. (JP-2001-157574 – see IDS and attached translation) in view of Johnsson et al. (Biophysical Journal 2001 80:313-323), Nishikawa et al. (Materials Research Society Symposium Proceedings 2002 724:N11.7.1-N11.7.6), and Maruyama et al. (Thin Solid Films 1998 327-329:854-856).

Maruyama et al., Nishikawa et al. and Shimomura et al. teach a honeycomb structured film comprised of biodegradable polymer and an amphiphilic compound/polymer that acts as a surfactant (see Maruyama et al. page 855 column 1 paragraph 1, Nishakawa et al. N11.7.3 paragraph 1, and Shimomura et al. paragraph 9; instant claim 4). Nishikawa et al. teaches polylactic acid and polycaprolactone as biodegradable polymers used in the film (see Nishikawa et al. N11.7.3 paragraphs 1 and 2; instant claims 5-6 and 8). Shimomura goes on to teach a larger set of biodegradable polymers that are suitable for use in the invention that include polycarbonates, polyethylene adipate, polyhydroxybutyric acid, polyethylene carbonate, and polybutylene carbonate (see paragraph 10; instant claims 5-8). Further the proportion of biodegradable polymer to amphiphilic compound/polymer is taught to be 10/1 by Nishikawa et al. and between 1/1 and 50/1 by Shimomura et al. (see Nishikawa et al. page N11.7.1 paragraph 3 and Shimomura et al. paragraph 9; instant claim 12).

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The three references do not teach phospholipids in particular as the amphiphilic compound.

Johnsson et al. teach that the phospholipid dioleoylphosphatidylethanolamine (L- α -phosphatidyl ethanolamine dioleoyl) forms an inverted hexagonal structure (honeycomb) in aqueous solution (see page 313 column 1 paragraph 1; instant claims 4, 9, and 11). Maruyama et al. teach that self-assembling molecules that form three-dimensional nanoscale structures are combined with polymers to form microscale features in structured films (e.g. honeycomb structures). L- α -phosphatidyl ethanolamine dioleoyl is an amphiphilic compound that would qualify as one such self-assembling molecule, is biodegradable itself, and as a phospholipid, has surfactant properties. It would therefore have been within the technical grasp of one of ordinary skill in the art at the time of the invention to utilize L- α -phosphatidyl ethanolamine dioleoyl in the invention of Maruyama et al., Shimomura et al., and Nishikawa et al. Thus claims 4-9 and 11-12 are obvious over Maruyama et al., Shimomura et al., Nishikawa et al., and Johnsson et al.

Claims 4 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Huang et al. (U.S. Patent No. 5,283,122), Nishikawa et al., and Maruyama et al.

Maruyama et al. and Nishikawa et al. teach a honeycomb structured film comprised of biodegradable polymer and an amphiphilic compound/polymer that acts as a surfactant (see Maruyama et al. page 855 column 1 paragraph 1, Nishakawa et al.

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N11.7.3 paragraph 1, and Shimomura et al. paragraph 9; instant claim 4). Nishikawa et al. teaches polylactic acid and polycaprolactone as biodegradable polymers used in the film (see Nishikawa et al. N11.7.3 paragraphs 1 and 2; instant claim 4). The two references do not teach phospholipids in particular as the amphiphilic compound.

Huang et al. teach that the phospholipid phosphatidyl ethanolamine (L- α -phosphatidyl ethanolamine) forms an inverted hexagonal structure (honeycomb) in aqueous solution (see claims 15 and 16; instant claims 4 and 9-10). Maruyama et al. teach that self-assembling molecules that form three-dimensional nanoscale structures are combined with polymers to form microscale features in structured films (e.g. honeycomb structures). L- α -phosphatidyl ethanolamine is an amphiphilic compound that would qualify as one such self-assembling molecule, is biodegradable itself, and as a phospholipid, has surfactant properties. It would therefore have been within the technical grasp of one of ordinary skill in the art at the time of the invention to utilize L- α -phosphatidyl ethanolamine in the invention of Maruyama et al., Shimomura et al., and Nishikawa et al. Thus claims 4 and 9-10 are obvious over Maruyama et al., Nishikawa et al., and Huang et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-6 of copending Application No. 10/580029. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a honeycomb film with a polymer selected from biodegradable aliphatic polyesters, aliphatic polycarbonate, polylactic acid, a polylactic acid-polyglycolic acid copolymer, polyhydroxybutyric acid, and polycaprolactone, along with a phospholipid selected from phosphatidyl ethanolamine, phosphatidyl choline, phosphatidyl serine, phosphatidyl glycerol, L- α -phosphatidyl ethanolamine and L- α -phosphatidyl ethanolamine dioleoyl. The polymer to phospholipid ratio claimed by copending Application No. 10/580029 is within the range claimed by the instant claims

.This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615